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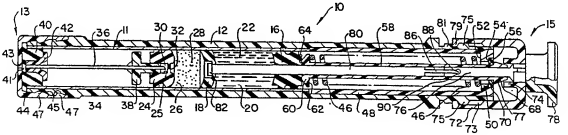

(57) Abstract

An automatic injector for mixing and injecting a plurality of ingredients comprises a housing (12) and a plurality of ingredients (22, 28) to be mixed normally stored separately within the housing, at least one of the ingredients being in liquid form. A flexible sealing structure (18) normally maintains at least two of the ingredients separately from one another and is flexibly deformable in response to a predetermined actuating procedure to permit the ingredients to mix within the housing. A needle (36) is normally contained within the housing and is drivable into a projecting position from the housing. A drivable plunger (16) is disposed within the housing and is capable of being driven to force the ingredients through the needle after the ingredients are mixed. A releasable drive assembly (46, 58) drives the needle from the protected position to the unprotected projecting position and drives the plunger (16) to force the ingredients through the needle.

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AUTOMATIC TWO-CHAMBER INJECTOR.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to automatic injectors and more particularly to automatic injectors of the type operated by the release of a releasable drive assembly.

2. Background of the Invention

Spring operated automatic injectors have been known for many years. The most extensive use of automatic injectors of this type has been to contain and inject a chemical warfare antidote. Other uses of injectors of this type include antidotes for bee stings and anti-arrhythmic medicaments, such as lidocaine.

More recently, it has been recognized that certain medicaments can be stored for longer periods of time if the ingredients comprising the same are stored separately and then mixed just prior to an injection. For example, certain dry medicaments are not stable for long periods when put in liquid form (e.g. when penicillin is mixed with water, it is stable for a rather short period of time before it rapidly decays). Therefore, there has been a need for mixing-type automatic injectors for containing such medicaments as military vaccines, nerve gas antidotes, human growth hormones, fertility drugs, anti-diabetic drugs, and anti-neoplastic agents. Several types of these medicaments consist of two or more ingredients which, ideally, should not be

stored in contact with each other for any significant length of time.

A number of automatic injectors which store two or more ingredients separately and then permit such ingredients to mix just prior to an injection have been introduced. For example, U.S. Patent No. 4,983,164 to Hook et al discloses a device which provides a piercable membrane disposed in an injector body for separating the body into two ingredient chambers. Each of the chambers contains a respective ingredient of a medicament to be injected. The membrane is ruptured to permit the two ingredients to mix just prior to an injection. Such rupturing of a membrane, however, is problematic in that pieces or particles of the membrane may separate from the whole membrane and be injected into the patient or, in some cases, obstruct the fluid path of the medicament through the injection needle. These occurrences could be quite dangerous to the subject using the injector.

Other such devices have been disclosed in U.S. Patent Nos. 4,822,340 and 4,820,286. These injectors accomplish a mixing operation prior to an injection by providing a substantially cylindrical passable stopper in slidingly sealed relation with a barrel. The passable stopper normally separates the ingredients to be mixed. During a mixing operation, the passable stopper is moved to a position in the barrel wherein grooves are provided in the side of the barrel. These grooves allow a liquid medicament to pass around the outer periphery of the passable stopper and mix with either a solid or another liquid ingredient in an adjacent chamber. After this mixing operation, the mixed ingredients can be injected. This type of injector, however, has a

number of disadvantages. First, in order for the passable stopper to be provided in slidably sealed relation to the cylindrical barrel, it is necessary for the passable stopper to have a sufficient axial length. In other words, if the cylindrical passable stopper were merely a flat disc, the passable stopper might not remain in coaxial alignment with the barrel as it might be caused to rotate about an axis substantially perpendicular to that of the longitudinal axis of the barrel. As a result, the total length of the stopper, and, hence, the device as a whole must be increased.

Second, it is known in these devices, that it is necessary to provide an additional volume of gas or space, in the chamber which contains the solid or freeze dried ingredient, that is substantially equal in size to the passable plunger. That is, the chamber within the injector which contains the solid ingredient must be provided with sufficient space to accommodate the passable plunger since the passable plunger must move into this chamber in order to align itself with the aforementioned grooves and permit the ingredients to mix. In other words, in addition to the amount of gas inherently provided with the solid ingredient, an additional amount of space must be provided to accommodate the passable plunger. As a result, since the passable plunger is relatively large, a significant amount of air is provided in the solid ingredient chamber. Such excessive amounts of air or gas provided within an ingredient chamber of an injector is undesirable since it may be injected into the patient, and may thereby cause harmful results if the air is injected into a vein or artery.

Third, since the bypass passages or grooves provided in the barrel are relatively narrow, it may take a relatively significant amount of time for a liquid ingredient to bypass the passable stopper and completely dissolve a solid ingredient.

SUMMARY OF THE INVENTION

It is an object of the present invention, therefore, to overcome the problems described above. Such object is accomplished by providing an automatic injector comprising a substantially elongate housing and a plurality of ingredients to be mixed and injected disposed within the housing. At least one of the ingredients is in liquid form, and a seal normally maintains the ingredients separately from one another. The seal is flexibly deformable to permit the ingredients to mix. A needle is normally disposed in a protective position within the body and is drivable into a projecting position from the body. A drivable plunger is disposed within the body and is operable to force the ingredients through the needle after they are mixed. Finally, a releasable energy source is capable of driving the needle from its protected position to the projecting position and is also capable of driving the plunger to force the ingredients through the needle.

The injector of the present invention is compact and easy to use. In addition, it accomplishes mixing of ingredients before an injection while inducing a gentle turbulence within the ingredients to assist mixing and dissolution of a solid ingredient if one is provided. This gentle

turbulence is an effective way to accomplish mixing of some of the more delicate medicaments such as human growth hormone, which can be adversely effected by a more vigorous manual shaking of the injector body as is required by many prior art devices. In addition, the device is constructed to have a very low level of gas or air space in the freeze dried or solid ingredient chamber. The device is also specifically designed to have a very low dead space (i.e., the volume of drug not injected into the patient after firing the device). This is particularly important when considering the high cost of some of the drugs used in conjunction with the injection device of the present invention, such as human growth hormones and the like.

These and other objects of the present invention will become more apparent during the course of the following detailed description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be best understood with reference to the accompanying drawings wherein illustrative embodiments are shown.

FIGURE 1 is a longitudinal view, partly in section, of an automatic injection device embodying the principals of the present invention and showing the same in its normal storage condition;

FIGURE 2 is a view similar to FIGURE 1, but showing the injector provided with a protective needle cover at the forward end thereof.

FIGURE 3 is a view similar to FIGURE 2, but only partly in section and showing the injector in a second stage of an operating sequence.

FIGURE 4 is a view similar to FIGURE 3, but showing the injector in a third stage of operation.

FIGURE 5 is a view similar to that of FIGURE 4, but showing the injector in a fourth stage of operation.

FIGURE 6 is a view similar to FIGURE 5, but showing the injector in a fifth stage of operation.

FIGURE 7 is a view similar to FIGURE 6, but showing the injector in sixth stage of operation.

FIGURE 8 is a view similar to FIGURE 7, but showing the injector in a seventh and final stage of operation.

FIGURE 9 shows a longitudinal sectional view of a second embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Referring more specifically now to FIGURE 1, it can be seen that the injector, generally indicated at 10, has an elongate generally tubular body or housing 12. Body 12 has a forward end, generally indicated at 13, from which a needle can project and a rearward end 15 which is provided with actuating means for the injection. A cartridge 11, can be placed at a forward position within body 12. The cartridge 11 includes a glass or plastic sleeve 14. Provided within the sleeve 14 is a plunger 16 normally positioned towards a rearward end thereof as shown in FIGURE 1. Plunger 16 is slidably moveable forwardly in sealed relation to sleeve 14.

Spaced forwardly of plunger 16 is a flexible wall member 18, which normally separates two different ingredients stored in the injector 10. Flexible wall member 18 is moveable rearwardly within sleeve 14 toward plunger 16. A space within sleeve 14 provided between plunger 16 and flexible wall member 18 constitutes a liquid ingredient chamber 20 which contains a liquid medicament 22 therein.

Spaced forwardly of flexible wall member 18 is a retaining plunger 24. Disposed between retaining plunger 24 and flexible wall member 18 is a solid ingredient chamber 26 containing a solid ingredient 28. Retaining plunger 24 is forwardly movable in slidably sealed relation with respect to sleeve 14. Ingredient chamber 26 can also be provided with a liquid ingredient if so desired.

Retaining plunger 24 is provided with a central bore 30 which substantially extends through a central axis of the plunger and is defined by an inner surface 25. Central bore 30 does not extend completely through retaining plunger 24, as the retaining plunger has a thin piercable portion 32 closing off central bore 30 to maintain the solid ingredient 28 in a substantially sealed condition in the solid ingredient chamber 26.

Forwardly disposed of retaining plunger 24 is an air or gas chamber 34, which contains needle 36. While chamber 34 can be filled with air, it is preferred for such chamber to be filled with an inert gas, such as nitrogen, to reduce the likelihood of oxygen permeating into the solid ingredient chamber 26 and thereby potentially reduce the shelf life of solid ingredient 28. The rearward end of needle 36 is held by a needle holder 38 preferably secured thereto by an adhesive or the

like. Needle holder 38 is received by central bore 30 of retaining plunger 24 and is capable of slidably moving with respect thereto in a manner which permits the rearward end of needle 36 to pierce piercable portion 32 of retaining plunger 24 during operation of the injector as will be described in greater detail later. The forward end 13 of the injector 10 is provided with a sealing bush 40 which forwardly confines gas chamber 34. Sealing bush 40 is provided with a central recess which receives a needle guide 42. The central recess is closed off by a thin piercable central membrane 41 of sealing bush 40 which can be pierced by the forward tip of needle 36. Needle guide 42 is substantially cone shaped and has a central bore therethrough which normally holds the forward end of the needle when the injector is in storage. When the injector is activated, needle 36 projects forwardly within body 12 and through needle guide 42 which maintains needle 36 in slidable relation therethrough during that process.

The injector 10 has an end cap 44 which is provided with projects 47 provided on the inner surface thereof, which cooperate with grooves 45 provided on the exterior surface of body 12 at forward end 13 so that end cap 44 is secured to body 12 at the forward end. The end cap 44 helps maintain the needle in sterile condition by keeping sealing bush 40 tightly secured to the forward end of the body 12 in sealed relation. End cap 44 has a central orifice 43 through which the needle 36 travels when projected from the forward end of the body.

The rearward portion of body 12 carries therein a releasable energy source or drive assembly

for driving the needle from its protected position within the body to an unprotected projecting position from the forward end of the body. The releasable drive assembly also drives plunger 16 forwardly to force the ingredients through the needle and into the flesh of a subject. The releasable drive assembly is mainly comprised of a releasable coil spring 46 which is normally in a compressed condition, as shown in FIGURE 1. It can be appreciated that only the forward and rearward portions of spring 46 are shown. Disposed between the releasable coil spring 46 and body 12 is a sleeve-like spring casing 48 which is secured to the inner surface of the rearward portion of body 12. The rearward portion of spring casing 48 has an inwardly projecting annular portion 50, which has a forward annular face 52. Annular portion 50 is provided with an annular recess 54, which receives a ring washer 56.

Extending through releasable coil spring 46 is an elongate cylindrical collet member 58. Collet member 58 is hollow and has an outwardly projecting head portion 60 at the forward end thereof. Head portion 60 has a rearwardly facing surface 62 which provides a forward bearing surface for releasable coil spring 46, which is normally maintained in its stressed condition between the rearward surface 62 of head portion 60 and face 52 of annular portion 50. Head portion 60 also has a forward surface 64 which bears against the rearward end of plunger 16.

The collet member 58 may be of any conventional configuration; however, it is preferably constructed of plastic material in a manner disclosed in U.S. Patent No. 3,795,061, the

disclosure of which is hereby incorporated by reference into the present specification. The collet member is hollow and has its rearward end divided, as by a slot (not shown), into two or more flexible portions. Formed on the rearward end of the flexible portions are arcuate locking wedges 68 having forwardly facing locking surfaces 70 which engage a rearwardly facing annular surface of washer 56 provided in annular recess 54 of annular portion 50.

The releasable energy source also includes a releasing mechanism which is in the form of a tubular releasing member 72. The releasing member 72, as shown, extends over the rearward end of body 12 and extends forwardly for a short distance in surrounding relation thereto so as to define a rearward portion of the exterior of the device. Accordingly, the tubular releasing member 72 may also be considered part of the housing of the injector (which also includes body 12 and end cap 44) as well as part of the releasable energy source.

As shown, the releasing member 72 is mounted for movement between a rearward storage position and a forward actuating position. As shown, the forward end of the tubular releasing member 72 is provided with a series of spaced axially extending grooves 73 in the inner periphery thereof for receiving ridge or ridges 75 on the exterior periphery of the rearward portion of body 12. The forwardmost end of releasing member 72 is provided with an inwardly projecting portion 79 which is normally contained between outwardly projecting ridge 81 on the outer surface of body 12 and ridge 75. The ridge 81 normally limits forward movement of releasing member 72. The rearward end

of the releasing member 72 is provided with inner forwardly projecting annular portion 74, which is disposed to engage the rearwardly facing segmental frusto-conical surfaces 77 of the locking wedges 68.

It can be seen that when the releasing member 72 is manually moved from its storage position, as shown, forwardly into its actuating position, the inwardly projecting portion 79 will ride over ridge 81 and projecting portion 74 will engage the segmental frusto-conical surfaces 77 of the locking wedges 68 causing the locking wedges to move inwardly toward one another, thus moving the locking surfaces 70 of the wedges out of engagement with the washer 56, thus enabling releasable coil spring 46 acting on the head portion 60 of the collet member 58 to move the collet member 58 forwardly.

The releasable energy source also includes a forwardly extending safety pin 76 (not shown in section) sized to engage the interior surface of the rearward portion of the collet member 58 so as to prevent the two locking wedges 68 to move toward one another. The safety pin also includes an end cap 78 which, as shown, extends rearwardly from the rearward end of the housing body assembly defined by the releasing member 72. The end cap 78 is integrally inter-connected with safety pin 76 and is manually engageable for the release thereof out of the hollow inner portion of collet member 58.

Also provided in the body and extending through a central bore in plunger 16 as well as through the hollowed central portion of collet member 58 is an operating rod 80 (not shown in section). Operating rod 80 is substantially elongated and has a smooth cylindrical outer

surface. The forward portion of operating rod 80 has an enlarged diameter portion 82 integrally formed therewith or adhered thereto in a molding operation.

During manufacture of the injector, the enlarged diameter portion 82 is forced through a central orifice in flexible wall member 18 and is flexibly sealed thereto. It can be appreciated that flexible wall member 18 is substantially annular. It can be appreciated, however, that it is not necessary for the central orifice to extend entirely through the flexible wall member. That is, in another embodiment, it is possible for flexible wall member 18 to be provided with merely a recess (or a "blind hole") which is closed off, but nevertheless accepts the forward end 82 of operating rod 80 in secured fashion. A closed off member 18 provides added security to ensure that the liquid and solid ingredients do not permeate through the flexible member 18 prior to a mixing operation.

An inner annular surface defines the central orifice through the flexible member and sealingly engages the forward portion of outer operating rod 80 including enlarged diameter portion 82, which prevents disengagement of the forward end of operating rod 80 from flexible wall member 18. Preferably, the inner surface of the central orifice in member 18 has at least a portion thereof provided with small forwardly and inwardly projecting teeth-like members which permit the forward end of operating rod 80 to enter the orifice during manufacture, but prevents the operating rod from being pulled out of engagement with the flexible member when the operating rod 80 is moved rearwardly within body 12 during a mixing operation which will

be described later. Alternatively, it can be appreciated, that enlarged diameter portion 82 can be adhesively secured to operating rod 80, although this is not preferred as it is undesirable to have an adhesive exposed to the ingredients to be injected. The rearward end of operating rod 80 is provided with a narrowed diameter portion 86 which terminates rearwardly in a locking ball 88 having a diameter somewhat larger than narrowed diameter portion 86 but narrower than the major portion of operating rod 80.

The forward end of safety pin 76 is divided, and adapted to receive locking ball 88 in a spherical recess 90 therein. Locking ball 88 is kept within spherical recess 90 until safety pin 76 is manually removed from its safety position as will be described later.

The operation of the injector in FIGURE 1 is shown in conjunction with FIGURES 2-8. The injector shown in FIGURES 2-8 is identical to that shown in FIGURE 1, but is also provided with a protective needle cover assembly as disclosed in our prior patent Application Serial No. 07/936,236, which is hereby incorporated by reference.

The needle cover assembly includes a cover member 96 which is provided at the forward end of the injector. Cover member 96 is tubular and extends over the forward end of the injector for a short distance in surrounding relation thereto so as to define a forward portion of the exterior of the device. The cover member 96 is moveable in an axial direction with respect to body 12. Cover member 96 has an inwardly projecting annular portion 98 at its rearward end thereof which is adapted to slidably engage the exterior periphery of body 12 between

flanges 100 and 102. A coil spring 104 is provided between an inner surface 106 of cover member 96 and the forward end of the injector as defined by end cap 44. Coil spring 104 normally maintains cover member 96 in an extended position.

The operation of the device will now be described. In FIGURE 3, it can be seen that cap 78 can be manually engaged so as to rearwardly move safety pin 76. As safety pin 76 is moved rearwardly, operating rod 80 is pulled rearwardly along therewith. As operating rod 80 is moved rearwardly within the injector, flexible wall member 18 is forced through the liquid medicament 22 which is contained within liquid ingredient chamber 20. As shown in FIGURE 3, this movement through the liquid causes flexible wall member 18 to flex just slightly as a result of the viscosity and incompressibility of liquid ingredient 22. This flexion allows the liquid ingredient to bypass or escape around the exterior periphery of flexible wall member 18 and into solid ingredient chamber 26 as indicated by the arrows in FIGURE 3. Thus, it will be appreciated that the flexible deformation of flexible wall member 18 causes it to have at least a portion of its outer periphery become at least momentarily disengaged from sleeve 14 and permit mixing of the solid and liquid ingredients. The operating rod 80 is moved rearwardly until flexible wall member 18 comes into abutment with the forward surface of plunger 16. At this point, operating rod 80 can move no further. As shown in FIGURE 4, when the user further withdraws cap 78, safety pin 76 eventually becomes disengaged from operating rod 80 as the spherical recess portion 90 of safety pin 76 is forcibly pulled out of engagement with locking

ball 88. Thus, safety pin 76 can be completely removed and discarded.

The next step of operation is shown in FIGURE 5. Here the injector is shown in a condition in which cover member 96 is engaged with an area of flesh to be injected and forced against the patient so that coil spring 104 is compressed.

The next two stages of operation are discussed in conjunction with FIGURES 6 and 7. It can be appreciated that the releasing member 72 has actuated the device, as shown in FIGURE 6, by being pressed by the user inwardly towards body 12 so that projecting members 74 engage the rearwardly facing segmental frusto-conical surfaces of the locking wedges 68 (see FIGURE 5). Locking wedges 68 were moved inwardly toward one another, thus moving locking surface 70 of the wedges out of engagement with the washer 56, and enabling the releasable coil spring 46 acting on the head portion 60 of collet member 58 to move the collet 58 forwardly. As a result, under the stress of coil spring 46, plunger 16 along with flexible wall member 18 will be driven forwardly within the body. During this initial movement of plunger 16, the mixed ingredients are compressed between plungers 16 and 24, and such compression causes plunger 24 and needle 36 to travel within needle guide 42, pierce the central membrane 41 of sealing bush 40 and enter the tissue of the patient. During the initial forward movement, it can be appreciated that there is a need to get rid of any air that may be in chamber 34, since such air might not be sufficiently compressible to permit forward movement of plunger 24 and needle 36. Therefore, referring back to FIGURE 1, sealing bush 40 is sufficiently flexible

to permit air to escape between its outer periphery and sleeve 14 and body 12. Air can then travel between body 12 and end cap 44, or through orifice 43, and escape to atmosphere. This construction is described in more detail in our previously filed PCT Application No. GB92/00081, which is hereby incorporated by reference.

As previously described, during the initial forward movement of needle 36, the retaining plunger 24 is driven forwardly as a result of the compression of the mixed ingredients. When retaining plunger 24 is initially moved forwardly within the injector, the needle holder 38 does not move relative thereto. Rather, the engagement of needle holder 38 with the surface 25 defining central bore 30 within retaining plunger 24 is sufficient to hold the rearward end of needle 36 in slightly spaced relation to piercable portion 32. This remains true even as the forward end of needle 36 comes into abutment with central membrane 41 of sealing bush 40 and pierces the same. That is, the friction between the surface 25 and needle holder 38 is sufficient to retain the rearward end of needle 36 in spaced relation from portion 32 during the piercing of central membrane 41, as there is less force required for needle 36 to pierce central membrane 41 than for plunger 24 to move relative to holder 38.

The forward motion of needle holder 38 causes it to eventually reach the needle guide 42. In this position, needle 36 is fully projecting from the forward end of the injector, and the continued forward movement of collet 58, plunger 16, flexible wall member 18, further compresses the medicament to cause retaining plunger 24 to move forwardly so that

piercable portion 32 is eventually pierced by the rearward end of needle 36 to permit the mixed ingredients to enter the rearward end of the needle. Further forward movement of the plunger 16 then forces the mixed ingredients through needle 36 and into the tissue of the patient.

FIGURE 8 shows the final stage of the injection operation. Here it can be seen that rigid cover member 96 is outwardly moved by the operation of coil spring 104 when the injector is removed the skin or surface of the user. The rigid cover member 96 covers needle 36 to prevent unwanted contact with the needle after an injection. It also advantageously hides the needle from view.

It can be appreciated that the present invention permits effective and efficient mixing of two ingredients. No piercing or cutting of an isolating membrane is required to effectuate such a mixture, and as a result, no particles of such membrane are injected into the patient or block passage of medicament through the needle. It can be appreciated, however, that other means of permitting the liquid solution to travel between the member 18 and body 12 to effectuate such mixing can be used. For example, it is also possible to provide a less rigid body 12 and sleeve 14 in addition to a lever provided on the exterior of the device which can be pressed to distort the body into an oval shape, thereby causing a by-pass conduit to be created between element 18 and the tube.

It should be noted that while the present application discloses to provision of just two ingredients to be mixed, three or more ingredients an also be provided and mixed in a similar manner.

For example, operating rod 80 can be adapted to carry with it two or more flexible wall members 18.

A second embodiment of the present invention is shown in FIGURE 9. This device functions substantially in the same manner as described in the first embodiment, and only the differences will be described herein. The same numerals used in the description of the first embodiment are used to indicate the same parts in this second embodiment. This injector is provided with a solid ingredient 202 contained within solid ingredient chamber 204 and a liquid ingredient 206 contained in liquid ingredient chamber 208. Also included is a substantially elongate cylindrical drive pin 210 having an enlarged diameter portion or snap ring 212. The drive pin 210 is disposed in the solid ingredient chamber 204. Also provided is a needle 214 disposed in the liquid ingredient chamber 208. When the device is actuated by manually removing cap 78, which carries safety pin 276, and depressing releasing member 72 as described in the first embodiment, the collet member 58 is driven forwardly and bears against plunger 16. Drive pin 210 extends through a center bore in plunger 16, and snap ring 212 of drive pin 210 prevents the plunger from sliding over drive pin 210 initially. As a result, forward movement of plunger 16 causes forward movement of drive pin 210. Fixed to the forward end of drive pin 210 is a flexible member 218 having a piercable central portion 220. Needle holder 38 is received in a forwardly facing central orifice in flexible member 218, much in the same manner such needle holder is received by retaining plunger 24 in the first embodiment. Movement of drive pin 210 forces flexible element 218 and needle

holder 38 forward so that the forward end of needle 214 pierces the central thinned portion of sealing bush 40. In can be appreciated that during this forward motion of the flexible element 218 through the liquid ingredient chamber 208, the liquid ingredient 206 is forced around the outer periphery of flexible element 218 and into solid ingredient chamber 204 so that the ingredients mix. Flexible element 218 permits such mixing as it flexibly deforms as a result of the incompressibility and viscosity of the liquid ingredient. It can be appreciated that when liquid ingredient 206 is provided into solid ingredient chamber 204, there may be some expansion of ingredient chamber 204 by relative rearward motion of plunger 16 with respect to flexible element 218 in order to accommodate the added amount of ingredient (liquid) therein.

Once the needle holder 40 reaches the forward end of the injector so as to bear against needle guide 42, the rearward end of needle 214 pierces central portion 220 of flexible element 18. The mixed ingredients are then free to enter the rearward end of needle 214. It can be seen that the forward end of drive pin 210 is forked so that it does not interfere with the rearward end of needle 214 or with mixing. Continued forward motion of collet 58 under the force of spring 46 causes plunger 16 to ride over snap ring 212 and slide along drive pin 210 to dispense the medicament through the needle and into the flesh of the patient. This design reduces the total length of the device by removing the separate gas chamber in which the needle was contained in the first embodiment. As shown, this second embodiment does not require air to be removed for actuation. In

addition, it can be appreciated that while in the first embodiment mixing is accomplished by a manual moving of flexible element 18, in the second embodiment such mixing is accomplished automatically in response to the release of the releasable drive assembly.

As an alternative in the second embodiment, it can be appreciated that plunger 16 can have the rearward end thereof sealed off much in the same way as flexible member 218. In this case, drive pin 210 would not extent completely through the plunger 16, but would be only partly through. The rearward end of drive pin 210 can also be provided with a point so as to puncture the sealed off portion much in the same way that the rearward end of needle 214 punctures portion 220 before the medicament is dispensed. As a third alternative, the plunger 16 can remain as shown in Figure 9, but an added plastic seal can be provided, either forwardly or rearwardly of the plunger 16, and which breaks in response to plunger movement. These aforementioned alternatives help maintain solid ingredient 202 free from oxygen.

Finally, it can be appreciated that in both of the aforementioned embodiments, it is possible to provide the plunger adjacent the solid ingredient chamber or the drive pin with a groove (or similar feature) to allow evaporation of a liquid originally placed in the solid ingredient chamber during manufacture prior to a freeze drying operation. For example, during the manufacture of the injector in the second embodiment, a forwardmost ridge 232 of plunger 16 is originally positioned in the rearward end of plastic or glass sleeve 14, while the more rearwardly disposed ridges are

extending rearwardly from sleeve 14. A groove (not shown) in ridge 232 permits gas to evaporate between the outer periphery of plunger 16 and sleeve 14. When the freeze drying operation is complete, plunger 16 is driven forwardly and into contact with the freeze dried ingredient. The more rearward ridges of plunger 16 seal off the ingredient chamber from atmosphere.

For purposes of background and elaboration of the present disclosure, the disclosures of the patents mentioned herein are incorporated by reference into the present specification.

It, thus, will be seen that the objects of this invention have been fully and effectively accomplished. It will be realized, however, that the foregoing preferred specific embodiment has been shown and described for the purpose of illustrating the functional and structural principles of this invention, and is subject to change without departure from such principles. Therefore, this invention includes all modifications encompassed within the spirit and scope of the following claims.

WHAT IS CLAIMED IS:

1. An automatic injector for mixing and injecting a plurality of ingredients comprising:

a housing (12);

a plurality of ingredients (22, 28) to be mixed normally stored separately within said housing;

a flexible sealing structure (18) for normally maintaining at least two of said ingredients (22, 28) separately from one another and being flexibly deformable in response to a predetermined actuating procedure to permit said at least two ingredients to mix within said housing;

a needle (36) normally contained within said housing and being drivable into a projecting position from said housing (12);

a drivable plunger (16) disposed within said housing (12) and capable of being driven to force said ingredients through said needle (36) after said at least two ingredients are mixed; and

a releasable drive assembly (46, 58) for driving said needle (36) from said protected position to said unprotected projecting position and for driving said plunger (16) to force said

ingredients (22, 28) through said needle (36) and into the flesh of an individual.

2. The automatic injector as claimed in claim 1, wherein a first of said at least two ingredients (22) is in a liquid form and said flexible sealing structure (18) is movable through said liquid ingredient (22) so that a viscosity of said liquid ingredient causes said flexible deformation of the sealing structure to permit said at least two ingredients (22, 28) to mix.

3. The automatic injector as claimed in claim 2, wherein a second of said at least two ingredients (28) is in a solid form.

4. The automatic injector as claimed in claim 3, wherein a total of two ingredients are provided within said housing.

5. The automatic injector as claimed in claim 1, wherein said housing further comprising an gas chamber (34) in which said needle (36) is normally stored.

6. The automatic injector as claimed in claim 5, further comprising a seal (40) which permits air normally contained in said gas chamber (34) to escape from said housing (12) prior to said drive assembly (46, 58) driving said plunger (16) to force said ingredients through said needle (36).

7. The automatic injector as claimed in claim 2, wherein said liquid ingredient (22) and said needle (36) are normally stored in a same chamber (208) within said housing (12).

8. The automatic injector as claimed in claim 1, further comprising a needle cover (96) disposed at a forward end of said housing for covering said needle (36) after said needle is driven into said projecting position from said housing (12).

9. The automatic injector as claimed in claim 2, wherein said flexible sealing structure (18) is movable through said at least one liquid ingredient (22), and a viscosity of said at least one liquid ingredient causes said flexible deformation of said flexible sealing structure (18) to permit said ingredients to mix when said sealing

structure is moved through said at least one liquid ingredient.

10. An automatic injector for mixing and injecting a plurality of ingredients comprising:

a housing (12);

a plurality of ingredients (22, 28) to be mixed normally stored separately within said housing, a first of said ingredients (22) being in liquid form;

a flexible sealing structure (18) for normally maintaining said liquid ingredient (22) separate from at least one other ingredient (28) within said housing, said sealing structure (18) being movable through said liquid ingredient (22) in a manner which causes flexible deformation of said sealing structure to permit said liquid ingredient to mix with said at least one other ingredient (28);

a needle (36) normally disposed in a protected position within said housing (12) and being drivable into an unprotected projecting position from said housing;

a drivable plunger (16) disposed within said housing and being operable to force said ingredients through said needle (36) after said

liquid ingredient and said at least one other ingredient (22) are mixed; and

a releasable drive assembly (46, 58) for driving said needle (36) from said protected position to said unprotected projecting position and for driving said plunger (16) to force said ingredients through said needle and into the flesh of an individual.

11. The automatic injector as claimed in claim 10, wherein said at least one other ingredient (28) is in a solid form.

12. The automatic injector as claimed in claim 11, wherein a total of two ingredients are normally stored in said injector, said two ingredients including said first liquid ingredient (22) and said solid ingredient (28).

13. An automatic injector for mixing and injecting a plurality of ingredients comprising:

a substantially elongate housing (12) having a longitudinal axis;

a plurality of ingredients (22, 28) to be mixed normally stored separately within said housing

(12), at least one of said ingredients (22) being in liquid form;

a confinement (14), having a predetermined inner diameter, disposed within said housing and being in communication within said ingredients;

a sealing structure (18) having an outer periphery with substantially the same diameter as said predetermined inner diameter of said confinement (14) and being in normally resilient peripheral contact therewith so as to form a seal which normally maintains said ingredients (22, 28) separately from one another within said housing (12), said sealing structure (18) and said confinement capable of being brought out of said contact in response to a manual actuating procedure to permit said at least two ingredients (22, 28) to mix;

a needle (36) normally disposed in a protected position within said housing (12) and being drivable into an unprotected projecting position from said housing;

a drivable plunger (16) disposed within said housing and being operable to force said ingredients through said needle (36) after said ingredients are mixed; and

a releasable drive assembly (46, 58) for driving said needle (36) from said protected position to said unprotected projecting position and for driving said plunger (16) to force said ingredients through said needle and into the flesh of an individual.

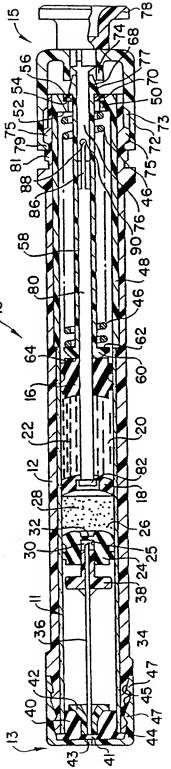

FIG. 1

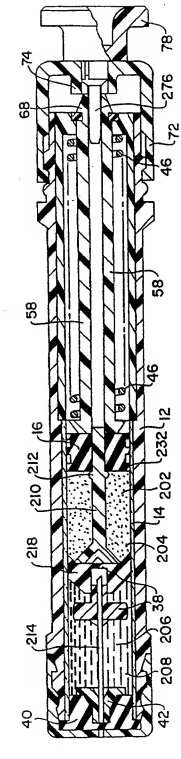

FIG. 9

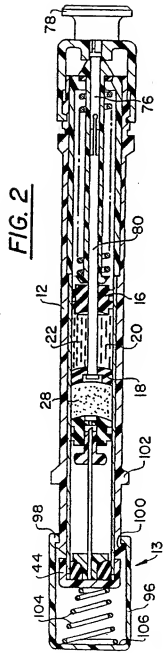

FIG. 2

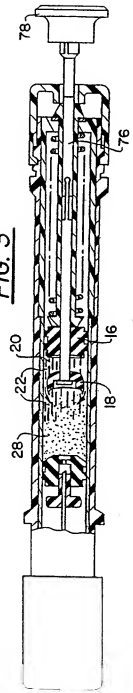

FIG. 3

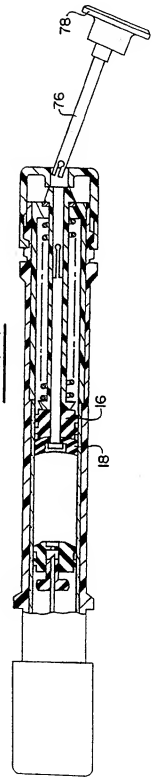

FIG. 4

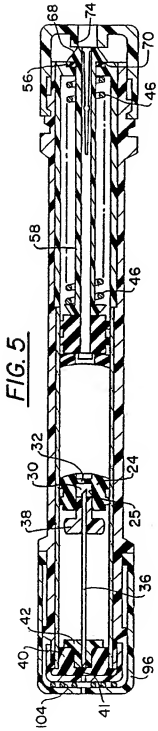

FIG. 5

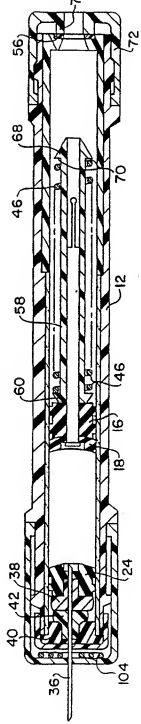

FIG. 6

FIG. 7

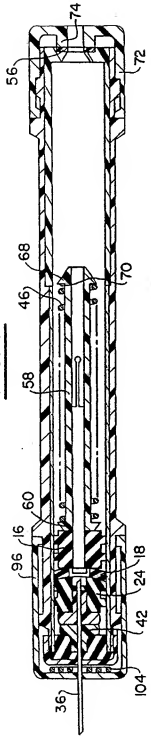
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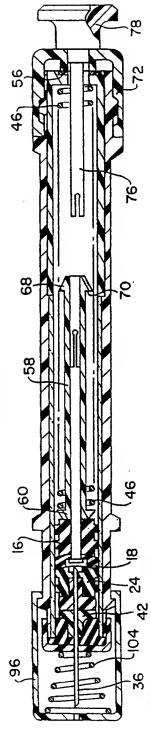
FIG. 8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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/GB 93/02303

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61M5/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,86 06966 (SURVIVAL TECHNOLOGY INC) 4 December 1986 see page 9, line 31 - page 10, line 9; figures	1-13
Y	EP,A,0 405 320 (ELKOM TOVARNA STIKALNIH NAPRAV) 2 January 1991 see the whole document	1-13
A	GB,A,2 096 464 (THE WEST COMPANY) 20 October 1982 see page 4, line 23 - line 84; figures 13-17	1-13
A	GB,A,1 193 846 (PENICILLIN GESELLSCHAFT DAUELSBERG & CO) 3 June 1970 see the whole document	1-13

[ ] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 January 1994	28. 01. 94
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (- 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (- 31-70) 340-3016	Authorized officer Clarkson, P

Form PCT ISA 210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inic. ional Application No
PCT/GB 93/02303

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-8606960	04-12-86	US-A-	4723937	09-02-88
		AU-B-	580238	05-01-89
		AU-A-	5950586	24-12-86
		CA-A-	1255561	13-06-89
		DE-A-	3682487	19-12-91
		EP-A,B	0225375	16-06-87
		JP-T-	62502874	19-11-87
EP-A-0405320	02-01-91	CA-A-	2019820	27-12-90
GB-A-2096464	20-10-82	US-A-	4479578	30-10-84
		CA-A-	1221063	28-04-87
		DE-A-	3213072	11-11-82
		FR-A,B	2503565	15-10-82
GB-A-1193846	03-06-70	BE-A-	697014	18-09-67
		US-A-	3511239	12-05-70